

201-14557



NCIC HPV
Sent by: Mary-Beth
Weaver

06/23/2003 02:50 PM

To: NCIC HPV, moran.matthew@epa.gov

cc:

cc:

Subject: "Petroleum Oxidates and Derivatives Thereof" Category: Revision of
Testing Plans and Robust Summaries



"Signs, Steven" <SAS@Lubrizol.com> on 06/23/2003 02:01:01 PM

To: oppt.ncic@epamail.epa.gov, Rtk Chem/DC/USEPA/US@EPA
cc: "Mandeville, Karen" <KDMA@Lubrizol.com>

Subject: "Petroleum Oxidates and Derivatives Thereof" Category: Revision of Testing Plans and Robust
Summaries

U.S. Environmental Protection Agency

P.O. Box 1473

Merrifield, VA 22116

Attention: Chemical Right-to-Know Program

Re: Revision of Testing Plan and Robust Summaries for the "*Petroleum Oxidates and Derivates
Thereof Category*" in response to EPA and public comments

To Whom It May Concern,

The Lubrizol Corporation thoughtfully considered the comments provided by the Environmental Protection Agency (EPA) and the public on the testing plan and robust summaries for "*Petroleum Oxidates and Derivates Thereof Category*" (posted on the HPV Challenge Program Web Site on April 1, 2003). In response to these comments Lubrizol has revised both the testing plan and robust summaries with the following comments.

Category Justification

The EPA did not agree with the subcategory grouping of the petroleum oxidates based upon the differences in molecular weight range, carbon chain length, and physicochemical properties. However, considering the definition of a chemical category in the EPA guidance document "Development of a Chemical Category" Lubrizol believes that the subcategory grouping is justified based upon the similarity in functional groups with a predictable pattern within each subcategory. Lubrizol will reassess the adequacy of this category approach given the outcome of the proposed environmental fate, environmental toxicity and health-related testing.

Public comments suggested that data from the API "Waxes and Related Materials Category" could be used as read-across to the "Petroleum Oxidates and Derivates Thereof Category". However, the oxidative process used in the former category results in a mixture of materials with

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a physicochemical profile distinct from the petroleum waxes. Therefore, it can not be assumed that there is a significant overlap in the hazard profile of these two categories of petroleum derivatives.

Health Effects

The EPA suggested that additional gene mutation data should be generated because the data originally submitted used only one strain of bacteria. Although the strain used in the submitted test is the most relevant for petroleum distillates, Lubrizol will perform additional gene mutation testing using all bacterial strains recommended in OECD 471 on the member of subcategory 1 and one member of subcategory 2.

The EPA disagrees with the proposed acute toxicity testing protocol for the member of subcategory 1, CAS No. 64742-98-9. The mammalian acute toxicity test was proposed in error. Lubrizol will not perform any additional acute mammalian toxicity testing on this category of materials.

The EPA disagrees with the proposal to apply read-across extrapolation between the two subcategories for the repeated-dose, reproductive and developmental toxicity endpoints. Lubrizol plans to use a tiered approach to testing as an animal sparing technique. Pending the outcome of the repeated-dose, reproductive and developmental toxicity tests on the single subcategory 1 chemical, Lubrizol may follow up with additional testing of a member of subcategory 2. This will be done if there is significant toxicity noted in the low molecular weight subcategory 1 material which is being proposed as the upper bound of toxicity.

Ecological Effects

The EPA recommends a chronic daphnia study in addition to the proposed acute daphnia study. Lubrizol plans to use a tiered approach to testing. Pending the outcome of the acute daphnia study, a follow-up with a chronic daphnia study may be performed.

A revised testing plan document and robust summaries incorporating the stated changes are being submitted with this letter.

<<Oxidate Test Plan- Revision 2003 2.doc>> <<ROBUST SUMMARIES FOR TOXICITY TESTING
ON- revision1.doc>>

Sincerely,

Steven A. Signs, Ph.D., DABT

Technical Contact for the HPV Chemical Challenge Program

Product Safety and Compliance

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